# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEBRASKA

STRECK, INC., a Nebraska corporation,	)
Plaintiff,	) 8:09CV410
V.	)
RESEARCH & DIAGNOSTIC SYSTEMS, INC., a Minnesota corporation,	) FINDINGS OF FACT AND ) CONCLUSIONS OF LAW
Defendant.	) )

This matter is before the court on Streck's appeal of a decision of the United States Patent and Trademark Office ("PTO"), Board of Patent Appeals and Interferences ("the Board") in Patent Interference No. 105,522 ("the Interference Action") under 35 U.S.C. § 146. The Board ruled in favor of defendant Research & Diagnostic Systems, Inc. ("R&D") on the issue of priority of invention of a hematology control composition. See Filing No. 1, Complaint, Exhibit ("Ex.") A, Judgment, Ex. B, Decision ("Bd. Dec."). Streck asserts that the Board's priority decision and resultant cancellation of its patent are erroneous. *Id.*, Complaint at 3.

This action involves essentially the same issues as those presented in *Streck v. R&D Diagnostic Systems, Inc.*, and *Techne Corp.* No. 8:06CV458 (D. Neb.), a case that was tried to a jury in October of 2009 ("the Infringement Action"). In that case, Streck alleged that R&D had infringed certain claims of its patent for a control composition for hematology instruments and R&D asserted the defense that it was the first to invent the control and counterclaimed for a declaration of invalidity. *See* Filing No. 1 and Filing No. 14 Complaint and Answer in 8:06CV458. The pending motions in both cases were consolidated for oral argument on August 23, 2010, with the purpose of consolidation of

the two actions for appeal to the United States court of Appeals for the Federal Circuit. See Filing No. 43, Order, in 8:09CV410 and Filing No. 384, text minute entry, in 8:06CV458.

The parties agree that this action can be resolved by the court on the infringement trial record and the Interference Action record. See Filing No. 30, Order at 1 (granting the parties' joint motion for admission of the record of the Interference Action); Filing No. 35, Memorandum and Order. The record now before court includes live testimony, evidence that was not presented to the Board, and evidence that conflicts with that provided to the Board. Over fifty exhibits were admitted in the infringement trial that were not considered by the Board in the Interference Action. See Filing No. 37, Index of Evidence ("Evid."), Affidavit of Merritt Westcott, Ex. A (comparison chart). Further, live witnesses presented testimony at the infringement trial that was not presented to the Board. See, e.g., T. Ex. 649 (John D. Nordin deposition excerpts); Filing No. 333, T. Tr. (Vol. IV) at 704-708 (testimony of Dr. Robert Langley); Filing No. 330, T. Tr. (Vol. I) at 5-115 (testimony of Constance Ryan); Filing No. 334, T. Tr. (Vol. V) at 882-925 (testimony of Thomas Oland); Tr. Ex. 650 (Marcel Veronneau deposition).

### I. FACTS

#### A. The Interference Action

An interference is a proceeding conducted by PTO pursuant to 35 U.S.C. § 135(a) in which Board determines questions of priority of inventions. 35 U.S.C. § 135(a) (when

 $<sup>^{1}</sup>$ The parties further agree that in 1996 the only issue in this case is whether R&D's projects on Johnson Controls 1 – 4 were reductions to practice. Filing No. 36, Streck Brief at 3; Filing No. 39, R&D Systems' Brief at 2.

<sup>&</sup>lt;sup>2</sup>Over objection by R&D, the court found that portions of the parties' arguments and briefs could also be made part of the record, for the limited purpose of providing background on appeal. Filing No. 35.

a patent application is filed that would interfere with any pending application or with any unexpired patent, the Director of the PTO is authorized to declare an interference to determine which party was the first to invent the claimed subject matter). An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa. 37 C.F.R. 41.203(a). The Board declared Interference No. 105,522 between U.S. Pat. Nos. 6,221,668 ("the '668 patent"); 6,200,500 ("the '500 patent"), 6,399,388 ("the '388 patent"); 6,403,377 ("the '377 patent"); and 6,406,915 ("the '915 patent") (collectively, "the Streck Patents") and U.S. Pat. App. No. 10/086,995 ("the Johnson or R&D application") on March 21, 2007. Filing No. 32 in Case No. 8:06CV458, Index of Evid., Ex. A, Declaration of Interference (Decl.).

Dr. Wayne Ryan and John Scholl are the inventors of the Streck Patents and have assigned their rights in the Streck Patents to Streck, Inc. See Filing No. 42, Response (admissions to R&D's proposed findings of fact). Ryan and Scholl filed their patent application on August 20, 1999 and were declared the senior parties in the Interference Action. Filing No. 32 in Case No. 8:06CV458, Ex. A, Decl. at 3. *Id.* Dr. Alan M. Johnson, Hematology Scientific Director at R&D, is the inventor of the control composition in the '995 application and is the junior party in the Interference Action. *Id.* 

In an interference proceeding, a "count" is the Board's description of the interfering subject matter that sets the scope of admissible proofs on priority. 37 C.F.R. § 41.201. Count 1, the sole count in the Interference Action, is identical to claim 46 of R&D's application and to claim 1 of the Streck '668 patent. See Trial Exhibits (T. Ex.) 2 & 119. The count provides:

A hematology control composition comprising:

- a) a stabilized reticulocyte component; and
- b) a fixed and stabilized white blood cell component capable of exhibiting a five-part differential.<sup>3</sup>

Filing No. 1, Complaint, Ex. B, Bd. Dec. at 6. R&D and Streck filed cross-motions for judgment on the basis of priority. *See id.* at 1. Both parties alleged conception and reduction to practice dates and Streck also alleged that R&D had abandoned, suppressed or concealed its invention. *Id.* at 3.

The Board determined that the "intended purpose" of the integrated control of the Count is to function as a hematology control for a hematology analyzer, that is, to allow a user to test whether a given hematology analyzer is correctly measuring the number of cells in a blood sample. *Id.* On November 2, 2009, the Board granted R&D's motion for priority and denied Streck's motion, finding:

Johnson has shown that it reduced to practice integrated controls #1 and #2 by 9 September 1996 and integrated controls #3 and #4 by 3 October 1996. All of these reductions to practice are prior to Ryan's earliest alleged reduction to practice. Ryan has not shown that Johnson abandoned, suppressed, or concealed the control composition.

Ryan has not shown that it exercised reasonable diligence in reducing to practice an invention of the Count from a time just prior to the first Johnson actual reduction to practice. Thus, even if Ryan had shown an earlier conception, Ryan cannot prevail.

*Id.* at 4-5. Further, the Board stated "we need not and do not evaluate whether Ryan has proven its alleged conception (or actual reduction to practice) dates." *Id.* at 30 n.16.

In making the finding that Johnson's integrated controls worked for their intended purposes, the Board relied on the testimony of Dr. Elkin Simson, R&D's expert witness,

<sup>&</sup>lt;sup>3</sup>The "five-part differential" refers to the subpopulations of white blood cells: lymphocytes, monocytes, neutrophils, basophils and eosophinils.

who concluded, after looking at the raw data from the testing of Johnson controls 1-4, that the stability shown was sufficient to demonstrate that each would have utility as a control. *Id.* at 17. The Board rejected Streck's position that "only scattergrams can show if there is interference between different cells types that would result in an inaccurate count." *Id.* at 23. The Board noted that "Dr. Johnson was combining known controls and thus was not starting from scratch in developing the integrated controls. In other words, Dr. Johnson knew what he was putting into the analyzer and would have known if an unexpected value was coming out." *Id.* at 24.

The Board credited the testimony of Dr. Simson over that of Streck's expert witness, Mr. James Janik. *Id.* at 25. After considering the testimony of both Dr. Simson and Mr. Janik, the Board agreed with Dr. Simson that scattergram analysis is not necessary to evaluate whether a control works for its intended purpose. *Id.* at 24-25. The Board "credited" Mr. Janik's testimony that scattergram data "can show where the errors lie" and acknowledged that scattergram data would likely be useful to "improve or closely evaluate an existing control or to find out why a control is not working properly," but found "if initial testing provides the expected values it is not apparent to us, and Ryan has not directed us to convincing evidence to show that scattergram data was required for Dr. Johnson to have come to the conclusion that controls #1- #5 were useful for their intended purpose." *Id.* at 25-26.

The Board also found that Dr. Ryan had not shown diligence. *Id.* at 30. It analyzed the diligence issue from the perspective that Dr. Ryan was the first to conceive the invention and the last to reduce it to practice, so Dr. Ryan had to show diligence from a time prior to his opponent's conception, and found:

Ryan has not shown, or even alleged, that it was diligent from a time prior to Johnson's first four reductions to practice. Ryan did not argue that there was a compelling reason to excuse its failure to take action. Instead Ryan acknowledges that its diligence began 5 February 1997. Accordingly, even were we to determine that Ryan was the first to conceive the invention, Ryan has not shown that it acted with due diligence during the entire critical period.

*Id.* at 30 (citations to record omitted). Because the Board found that the junior party, R&D/Johnson, had proved that it had reduced the invention to practice before the senior party's priority date, it placed the burden on Streck/Ryan to prove that R&D had abandoned, suppressed, or concealed the invention. *Id.* at 31.

# B. The Infringement Action

Before the interference was declared, Streck filed an action for patent infringement against Research and Diagnostic Systems, Inc., and Techne Corporation (collectively, "R&D") in this court on June 29, 2006. Filing No. 1 in 8:06CV458, Complaint. Streck alleged R&D manufactured and sold integrated control products that infringed certain claims of Streck's patents. *Id.* R&D denied infringement and alleged that the asserted claims of the Streck patents were invalid because, among other things, the control composition that is the subject of the claims had first been invented by Dr. Alan Johnson. See Filing No. 14 in 8:06CV458, Answer. This court declined to stay the Infringement Action pending the outcome of the interference proceeding and the two actions proceeded in both forums simultaneously for several years. See Filing Nos. 38, 51 & 133 in 8:06CV458, Orders

The Interference Action was tried to a jury from October 18, 2009, to October 29, 2009. See Filing Nos. 303, 304, 305, 308, 309, 310, 311, 313 in 8:06CV458, minute entries. The jury returned its verdict, in the form of answers to special interrogatories.

Filing No. 315 in 8:06CV458, Special Interrogatories (Verdict) at 2. The jury found, for each claim of the patent alleged to have been infringed, that R&D had not proved by clear and convincing evidence that Dr. Johnson was the first to invent the asserted claim.<sup>4</sup> *Id.* The Board issued its decision in the Interference Action five days after the receipt of the jury's verdict in the Interference Action. Filing No. 1, Complaint, Ex. B., Bd. Dec. at 3-4.

The evidence adduced at trial is summarized in this court's order denying R&D's motion for judgment as a matter of law or for a new trial in the Interference Action and need not be repeated fully here. See Streck, v. Research and Diagnostic Systems, Inc., and Techne Corp., No. 8:06CV458 (D. Neb.), Memorandum and Order entered on this date at 2 -12; see also Filing No. 330, Trial Transcript ("T. Tr.") (Vol. I); Filing No. 331, T. Tr. (Vol. II); Filing No. 332, T. Tr. (Vol. III); Filing No. 333, T. Tr. (Vol. IV); Filing No. 334, T. Tr. (Vol. V); Filing No. 335, T. Tr. (Vol. VI); Filing No. 336, T. Tr. (Vol. VII) and Filing No. 337, T. Tr. (Vol. VIII) in case No. 8:06CV458. Briefly, as relevant to the present appeal, the evidence adduced at trial showed that Dr. Ryan conceived the invention, an integrated control composition that would run on a machine that tested simultaneously for red blood cells, the five subtypes of white blood cells, platelets and reticulocytes, in late 1993, when he directed his laboratory assistant, Patrick Tran, to conduct experiments by adding reticulocytes to various control products with the objective of determining if the reticulocytes would interfere with the white cells or vice-versa. See Filing No. 331, T. Tr. (Vol. II) at 306-07 (testimony of John Scholl). The result of those experiments was the conclusion that it was feasible to add reticulocytes to a complete control "without interference from

<sup>&</sup>lt;sup>4</sup>The jury also determined that, with respect to damages, that a reasonable royalty was 12.5% and that Streck had failed to prove that "R&D's conduct was objectively reckless" as required for a finding of willful infringement. Filing No. 315 in 8:06CV458, Special Interrogatories at 4.

white blood cells." *See* Filing No. 330, T. Tr. (Vol. I) at 139 (testimony of Tran); *see also* Filing No. 331, T. Tr. (Vol. II) at 306-15 (testimony of Scholl); 392-95, 397-99 (testimony of Dr. Wayne Ryan); Trial Exhibits ("T. Exs.") 126, 130 at p. 5. Tran discussed the results of the experiments with his supervisor, John Scholl, and with Dr. Ryan and provided his observations and data to them. Filing No. 331, T. Tr. (Vol. I) at 140 (testimony of Tran); Filing No. 331, T. Tr. (Vol. II) at 397-98 (testimony of Ryan). Dr. Elkin Simson, an expert who testified on behalf of R&D, stated at trial that Dr. Ryan's 1993 experiment was a complete conception. Filing No. 336, T. Tr. (Vol. VII) at 1418-19. James Janik, Streck's expert witness, also expressed the opinion that the 1993 experiments were the conception of the idea. Filing No. 332, T. Tr. (Vol. III) at 596.

Dr. Alan Johnson testified he had conceived the invention in 1995. Filing No. 34, T. Tr. (Vol. VI) at 1059-60 (testimony of Dr. Johnson). Dr. Simson concurred that Dr. Johnson had fully conceived of the same invention in 1995 when he set forth a list of "possible projects" including a "CBC Control with Reticulocyte Capability." Filing No. 336, T. Tr. (Vol. VII) at 1416-1419; T. Ex. 1004. Accordingly, undisputed evidence at trial established that Dr. Wayne Ryan was the first to conceive the invention.

<sup>&</sup>lt;sup>5</sup>This testimony was contrary to Dr. Simson's position in the Interference Action, where he espoused R&D's argument that "Ryan [had] failed to prove that the work performed on [the 1993 project] constitutes a complete conception of the count. To the contrary, the unsuccessful conclusion of that project establishes that Ryan did not have a complete conception of the count." See Int. Paper No. 131 (Johnson Interference Opposition 7) at 5. In a sworn declaration, Dr. Simson gave the opinion that Dr. Ryan's 93321 project was not a conception of the invention of the Count:

In my opinion, with respect to [Dr. Ryan's] 1993 project, neither the data nor Dr. Langley's analysis of it establishes that a person of ordinary skill in the art as of November-December 1993 would have appreciated that it was feasible to make a control composition of Count 1.

The evidence shows that further experimentation such as stability studies were not pursued by Streck at that time because "it was just a fact gathering mission in a way, and the analyzers that we ran it on would not be the same analyzers down the road once they came out with it, and we were primarily interested in seeing if there is any interference." Filing No. 330, T. Tr. (Vol. I) at 143 (testimony of Tran). Between 1993 and 1997, Streck did not have "one instrument that could take one aspiration of a blood sample and give you all the results. That analyzer did not exist." *Id.* at 164. Instrument manufacturers began launching integrated hematology instruments in 1996. Filing No. 330, T. Tr. (Vol. I) at 34-35 (C. Ryan testimony). In 1996, Coulter developed, and Streck acquired, a module on which to run reticulocytes together with a white blood cell differential. Filing No. 331, T. Tr. (Vol. II) at 315 (testimony of Tran). Abbott launched the cell-Dyn 4000 for sale to the public in 1997. Id. at 352. Because it had a contract to provide controls for Abbott's instruments, R&D had been given prototypes of the instrument prior to the public release in order to work on controls for the instrument. Filing No. 332, T. Tr. (Vol. III) at 625 (testimony of Janik). Constance Ryan testified that hematology machines cost \$40,000 to \$150,000 Filing No. 330, T. Tr.(Vol. I) at 14.

The purpose of a control is to "monitor the performance of the machine." Filing No. 334, T. Tr. (Vol. VI) at 1085 (testimony of Dr. Alan Johnson); Filing No. 336, T. Tr. (Vol. VII) at 1421-22 (testimony of Dr. Elkin Simson) (stating the purpose of a control is to check "the performance of your machine"); T. Exs. 1-3. A control composition that "worked" would be one that lacked interference, with cells properly positioned, that was stable over time. Filing No. 331, T. Tr. (Vol. II) at 211 (testimony of Tran); Filing No. 333, T. Tr. (Vol. IV) at 754 (testimony of Langley). Janik and Langley both testified that in order to determine if

a control "worked," one would have to look at a scattergram. *Id.* at 758-59 (Langley); Filing No. 332, T. Tr. (Vol. III) at 588-93 (Janik). Dr. Simson, R&D's expert witness, conceded that analysis of scattergrams is necessary when developing a control. Filing No. 336, T. Tr. (Vol. VII) at 1352, 1419, 1422, 1426, 1427.

Scattergrams are visual representations of the positioning of cell populations by type, according to an instrument's mathematical algorithms (or software). Filing No. 330, T. Tr. (Vol. I) at 130 (testimony of Tran). The positioning is generally determined by cell size, shape, and the amount of light it scatters. *Id.* Based on the cells' relative positions, the scattergram displays the instrument's classification of the populations of the various types of cells. Filing No. 333, T. Tr. (Vol. V) at 758-60 (testimony of Langley)(stating that a scattergram is a graphical representation of the different cell types, "a pictorial representation of what the software or the algorithms have done," showing that the cell population is "in the areas where the computer algorithm of the instrument expects them to be"); Filing No. 332, T. Tr. (Vol. III) at 584-86 (testimony of Janik).

At trial, Mr. Janik explained that the problem is that "[t]he reticulocytes are small cells that can interfere at the bottom of where we are measuring white cells, so they could be called white cells [by the machine]." Filing No. 332, T. Tr. (Vol. III) at 602. The analysis of a scattergram will show if there is overlapping between the different cell types, known as interference, and the significance of the scattergrams is the ability to determine whether subpopulations of cells are at or near the thresholds set by the software algorithms of the instruments. T. Ex. 610 at S 0011846. The algorithms are designed to distinguish and enumerate each cell type by setting thresholds that define each cluster of cells. *Id.* (noting that "[i]t is critical for accurate value assignment and day to day and instrument to

instrument precision that the cell clusters are not sitting on the counting thresholds."). Dr. Ryan and Tran, as well as Streck's expert witnesses, James Janik and Dr. Robert Langley, all testified that scattergrams are the only means to determine whether such interference is occurring or is likely to occur in a given control composition that is being researched and developed. Filing No. 331, T. Tr. (Vol. II) at 404-05 (testimony of Dr. Ryan); Filing No. 330, T. Tr. (Vol. I) at 130 (Tran); Filing No. 332, T. Tr. (Vol. III) at 588-593 (Janik); Filing No. 333, T. Tr. (Vol. IV) at 758-60 (Dr. Langley). R&D's expert witness, Dr. Elkin Simson, agreed that scattergrams are necessary in designing a control. Filing No. 336, T. Tr. (Vol. VII) at 1419, 1426-27.

Dr. Janik testified that there are numbers behind all the dots on a scattergram that can be analyzed mathematically without looking at the visual representation. Filing No. 332, T. Tr. (Vol. III) at 650. Those numbers would be generated by the algorithm in the computer of the hematology instrument. *Id.* at 651 (explaining that the "dots are based on the number" and that "the algorithm separates the population and the dots in those gates are what the number is," so that "[t]he measurement of the individual cells determines where they fall in that plot. The algorithm tries to separate them by their populations, which then the ones that are inside one box become cell X and the ones in the other box become cell Y"). There is no evidence that Dr. Johnson did such a mathematical analysis, specific to an instrument's algorithms, on Johnson Controls 1 - 4.

John D. Nordin, R&D's Manufacturing Manager, testified that visual examination of scattergrams is necessary to R&D's quality control. T. Ex. 649 (Nordin deposition excerpts) at 35, 55-56, 70-72, 76. There is also evidence that shows that evaluation of scattergrams is a preliminary and indispensable step used and accepted by the industry in determining

whether a control being developed works for its intended purpose. Filing No. 333, T. Tr. (Vol. V) at 707-708 (testimony of Dr. Langley); Filing No. 332, T. Tr. (Vol. III) at 617 (testimony of Janik); T. Ex. 610 at S-001846-47.

R&D produced evidence that Dr. Johnson had performed experiments on an integrated reticulocyte control beginning in mid-1996. See T. Exs. 1039, 1061, and 1057. Dr. Johnson testified that the purpose of the experiments was "to test the idea to see if we could do—see if we could combine porcine reticulocytes with a control that we had—that preexisted, that we already manufactured for an Abbott instrument and see if we got any undue interference and stability problems." Filing No. 334, T. Tr. (Vol. VI) at 980. On July 17, 1996, Dr. Johnson made two samples containing a reticulocyte component and a white blood cell component (Johnson Controls 1 and 2), and his research assistant, Paul Nansen, ran those samples on an Abbott Cell-Dyn 4000 instrument. See T. Ex. 1039. In the six-page exhibit that memorializes the experiment, only the notation "CBC-3K U076 + RETIC 2 960507" at the top of the first page of the exhibit, indicates the formulation of the components in the sample. *Id.* at 1. The exhibit contains graphs, two sheets of raw data and a single scattergram for the experiment. *Id.* at 3-5; see also Filing No. 334, T. Tr. (Vol. VI) at 1082-83, 1087 (testimony of Dr. Johnson); Filing No. 335, T. Tr. (Vol. VII) at 1170 -71 (testimony of Nansen). There are no other scattergrams that would show whether there were shifts in cell population over time. See Filing No. 334, T. Tr. (Vol. VI) at 1083-1084 (testimony of Dr. Johnson).

Two more samples (Johnson Controls 3 & 4) were run on the STKS instrument from July through October 3, 1996. T. Ex. 1061. The only data that exists for the testing of Johnson Controls 3 & 4 are three pages of data attached to a 1998 memorandum from

Alan Johnson to R&D's upper management summarizing work done on "5D Controls with Reticulocytes" in 1996. *Id.* at 4-6; Filing No. 334, T. Tr. (Vol. VI) at 1064-65, 1067-68 (testimony of Johnson). The attached laboratory documents show that "5D3PL [and 5D3PN] + ret" were used in the samples. T. Ex. 61. There are no scattergrams that show results for the experiment, nor is there any testimony that Dr. Johnson reviewed scattergrams for the project. *Id.*, Filing No. 334, T. Tr. (Vol. VI) at 1068. None of the original data that would have been generated by the instrument during this experiment has been produced. Filing No. 334, T. Tr. (Vol. VI) at 1068-69 (Johnson testimony acknowledging that the data provided in T. Ex. 1061 was from a spread sheet he prepared). Dr. Johnson testified that in determining whether a control works, he looks at the reproducibility of the numbers. *Id.* at 978.

The only indication of the formulation, components, or relative percentages of components comprising the Johnson 3 & 4 samples is the found in the title "5D 3PL + RET" on the exhibit. Tr. Ex. 1061 at 5-6. Dr. Johnson testified that "5D3PL" and "5D3PN" were not standard products, but were prototypes. Filing No. 334, T. Tr. (Vol. VI) at 1069-70. No formulas for the prototypes are attached. *Id.* at 1070. Dr. Johnson acknowledged that R&D was having problems with some 5D (white cell differential) products at that time. *Id.* at 1071; see also T. Ex. 1045, 1046. A 5D composition was later abandoned by R&D as unworkable. See T. Ex. 1045 at RDS-15699 (noting "The 5D material which was to be sampled in Europe failed because of lymph-mono and lymph-baso flips [inaccurate WBC threshholding] . . . [b]ecause of these results this format is being abandoned."); see also Filing No. 334, T. Tr. (Vol. VI) at 1070-71 (testimony of Dr. Johnson).

Dr. Johnson's research assistant, Paul Nansen, testified that Dr. Johnson made up the vials and would have had to tell Nansen what the components were in order for Nansen to have made up the graphs or tables, but Nansen could not remember any specifics. *Id.* at 1173. Dr. Johnson's testimony regarding the components of the experimental compositions was vague and contradictory. Filing No. 334, T. Tr. (Vol. V) at 971, 979–80, 1069-72. He stated that he used commercial compositions and knew at the time what was in them but was not able to state with any specificity the percentages of each component or the buffers used. *Id.* at 1069-72. There is no evidence with respect to the ingredients, components, buffers or fixatives that comprised the prototypes "5D3PL" or "5D3PN" or R&D's commercial formulations at the time the tests on Johnson Controls 1-4 were performed. Diluents also affect how a control works. Filing No. 332, T. Tr. (Vol. III) at 606 (testimony of Janik).

Although Mr. Nansen testified that he reported his results to Dr. Johnson, and that he and Dr. Johnson thought the control "worked pretty good," he made no notation of that conclusion in his data. Filing No. 335, T. Tr. (Vol. VI) at 1173. Neither Mr. Nansen nor Dr. Johnson's superior, Dr. Thomas Detwiler, could recall the dates or specifics of any conversations in which they would have discussed the results of the integrated reticulocyte control experiments with Dr. Johnson. Filing No. 335, T. Tr. (Vol. VI) at 1173 (Nansen); Filing No. 335, T. Tr. (Vol. VI) at 1169-70 (Detwiler).

In December of 1996, Dr. Johnson reported to Dr. Detwiler that the tests on the Abbott Cell-Dyn 4000 had shown "good reticulocyte recovery with no degradation of the

<sup>&</sup>lt;sup>6</sup>The Board relied on Nansen's testimony that Dr. Johnson told him that at least Controls 1 - 4 were combinations of known commercial R&D products, noting that "it would have been reasonable for Dr. Johnson to have used stabilized products that were known to be useful in hematology analyzers and that were readily available to him." See Bd. Dec. at 27.

other parameters." T. Ex. 1045. However, Dr. Johnson's lab notes from January of 1997 show that there were continuing concerns regarding reticulocyte stability. T. Ex. 119 at RDS 14092-95. In the Spring of 1997, R&D continued to experiment with integrated controls. See T. Ex. 1049. In April of 1997, Dr. Johnson reported that samples tested on the Cell-Dyn 4000 "show[ed] unacceptable reticulocyte stability." T. Ex. 1052 at RDS-015706; see also Filing No. 334, T. Tr. (Vol. V) at 1087-89 (Dr. Johnson testimony); T. Ex. 1053 at 6; Filing No. 335, T. Tr. (Vol. VI) at 1209-10 (testimony of Dr. Detwiler). The goal for the following quarter was to "identify those conditions which increase the stability of reticulocytes in this combination without affecting the stability of other parameters." T. Ex. 1052 at RDS-015707. There were continued problems with reticulocyte stability and Dr. Johnson considered modifying the buffer or fixing the reticulocytes. Filing No. 335, T. Tr. (Vol. VI) at 1209-10 (testimony of Dr. Detwiler). Dr. Johnson reported "the project appears to have disappeared from priority lists and there are no plans at this time to build additional lots." T. Ex. 1057 at RDS-013680; Filing No. 335, T. Tr. (Vol. VI) at 1231 (testimony of Dr. Detwiler). There is no evidence that Dr. Johnson ever built any additional lots or made any modifications. See Filing No. 335, T. Tr. (Vol. VI) at 1231 (testimony of Dr. Detwiler).

As part of their employment with hematology instrument manufacturers Bayer/Siemens and Abbott, Dr. Langley and Mr. Janik review and comment on the sufficiency of prototype controls. Filing No. 332, T. Tr. (Vol. III) at 570-571, 583-84 (testimony of Janik); Filing No. 333, T. Tr. (Vol. IV) at 697-99, 702, 704-09 (testimony of Dr. Langley). James Janik testified that the documents in connection with the experiments on Johnson controls 1 & 2 were not sufficient to show that the controls worked for their intended purpose. Filing No. 336, T. Tr. (Vol. VII) at 1460. He stated that he could not "tell

from this data whether or not we are actually measuring reticulocytes, or if we're measuring some interference in the reticulocytes. It's impossible for me to make that conclusion." *Id.* at 1460-61. Additionally, he pointed out that the CBC-3K formulation used in the Johnson Controls 1 & 2 projects was the "trade formulation they had for the control they made for the Cell-Dyn 3000 analyzer." *Id.* at 1461. Although the composition was known to work on the Cell-Dyn 3000, that was not an indication that it wold work on the Cell-Dyn 4000, since the machines were totally different. Id. at 1462. In the predecessor instruments, the reticulocyte measurement was taken separately from the complete blood count measurement and white blood cell differential. Id. The 3K product used in Johnson Controls 1 & 2 had to be completely redesigned because it did not work with the new technologies used in the Cell-Dyn 4000 instrument. Filing No. 335, T. Tr. (Vol. VI) at 1250 (testimony of Mark Collins); Filing No. 336, T. Tr. (Vol. VII) at 1461-62 (testimony of Janik). Further, Janik testified that he reviewed the evidence that relates to R&D's experiments on Johnson Controls 3 & 4 and was unable to state that those compositions worked for their intended purpose as controls. Filing No. 336, T. Tr. (Vol. VII) at 1466. He stated, "they were relatively stable and something was being measured, but without further information about the formulation, about the open and closed vial stability, about the scattergrams so I could see what was being measured, no, I couldn't say that." Id.

R&D's expert, Dr. Elkin Simson, also reviewed the evidence and testified that his "conclusion from the analysis that I did was that the Johnson controls one and two worked as they would be expected to work because they were stable and gave results that would be expected purely on the variability of the analog over a period of time which exceeded fifty days." Filing No. 336, T. Tr. (Vol. VII) at 1373. Dr. Simson concluded that Johnson

Controls1 and 2 showed satisfactory stability over the testing timeframe of 55 days and Johnson Controls 3 and 4 showed satisfactory stability over the testing time frame of 86 days. Id. at 1372-73, 1375, 1377-78, 1382-83. Although Janik did not challenge Simson's conclusions on stability, he took issue with Simson's conclusions on interference, stating "I don't believe that we know what we're measuring there," so he could not state with certainty that the "reasonably stable fifty day" period was "really measuring reticulocytes." *Id.* at 1488.

Evidence also shows that R&D did not consider the 1996 and 1997 experiments to have been successful; after testing on Johnson Control 5 in late 1997, R&D did not attempt to make another sample of integrated reticulocyte control until 2003 and there is no evidence that it used any of the results from Dr. Johnson's 1996 and 1997 work. Filing No. 334, T. Tr. (Vol. V) at 1093-94, 1100 (testimony of Dr. Johnson); T. Ex. 93 at RDS-021353. Experiments performed in 1999 and 2000 show that R&D continued to have problems with interference that related to buffers used in an integrated control composition it prepared for the College of American Pathologists. Filing No. 334, T. Tr. (Vol. V) at 1061-64, 1100 (testimony of Dr. Johnson). As late as 2004, R&D records show that it was "in the process of feasibility testing of a variety of ideas to obtain and stabilize human reticulocytes in order to move towards the CBC plus retic products." T. Ex. 541 at RDS-021583.

Beginning in early 1997, Dr. Ryan and John Scholl worked on projects involving developing an integrated control with reticulocytes at Streck. Filing No. 331, T. Tr. (Vol. II) at 232 (testimony of Tran). Streck produced voluminous and meticulous evidence, including laboratory notebook entries, lab notes, data, and numerous scattergrams from testing the control substances on various hematology instruments, that showed that Dr.

Ryan and his staff developed integrated reticulocyte controls that worked for each of several machines beginning with Streck project 97034 in February 1997. See T. Ex. 648. Streck's expert witness. Dr. Robert Langley, testified that the numerical results of the experiments demonstrated that each control had sufficient stability. Filing No. 333, T. Tr. (Vol. IV) at 734-41, 750. Dr. Langley and Mr. Janik testified that they examined the scattergrams for the projects and that the cell populations were properly positioned in the scattergram without substantial interference. Id. at 750-54 (testimony of Langley); Filing No. 332, T. Tr. (Vol. III) at 622-23, 627-30 (testimony of Janik). R&D's expert, Dr. Simson, agreed at trial that Streck's 1997 experiments were successful reductions to practice. Filing No. 336, T. Tr. (Vol. VII) at 1386 (stating that "Dr. Ryan had demonstrated previously, as we heard in this trial, controls that would work for their intended purpose sometime in late 1997"). The evidence shows that Streck continued to work on and refine the integrated reticulocyte controls from shortly after it first acquired a machine on which to test the integrated controls in late 1996, until Dr. Ryan filed the patent application in August of 1999. See Tr. Ex. 144 & 147 (showing experiments on an integrated control for the Sysmex XE 2100); Filing No. 331, T. Tr. (Vol. II) at 197-203 (testimony of Tran); T. Ex. 148 at 168-171; T. Ex. 151; Filing No. 331, T. Tr. (Vol. II) at 271-73 (testimony of Christopher Taylor) (showing experiments on an integrated control for use on an Abbott CD-4000); T. Ex. 137 at 52-55; T. Ex. 157; Filing No. 331, T. Tr. (Vol. II) at 204-10 (showing experiments on an integrated control for use on a Bayer Advia 120 instrument).

Streck announced it was preparing to market an integrated reticulocyte control at trade shows in the summer of 1999. Filing No. 330, T. Tr. (Vol. I) at 45-46. It filed its patent application in August 1999 and commercially released its first integrated reticulocyte

control (Stak-Chex Plus Retics®) shortly thereafter, in December of 1999. T. Ex. 190; Filing No. 331, T. Tr. (Vol. II) at 326-328 (testimony of John Scholl). Within the next year, Streck introduced integrated reticulocyte controls for a number of other instruments. Tr. Exs. 194-195; Filing No. 331, T. Tr. (Vol. II) at 328-29 (testimony of John Scholl).

# II. DISCUSSION

#### A. Law

#### 1. Standard of review

Under 35 U.S.C. § 146, the losing party in an interference proceeding may file a complaint in district court for review of the Board's interference proceedings and the presentation of new evidence. See Winner Int'l Royalty Corp. v. Wang, 202 F.3d 1340, 1345 (Fed. Cir. 2000) (describing a § 146 action as a hybrid of an appeal and a trial de novo). In contrast to a direct appeal to the Federal Circuit under 35 U.S.C. § 141, the parties are not limited to the evidentiary record before the Board in an appeal under § 146. Koninklijke Philips Elec. N.V. v. Cardiac Science Operating, 590 F.3d 1326, 1332 (Fed. Cir. 2010). In reassessing the Board's ultimate conclusion on priority, this court can take new evidence. See, e.g., Winner, 202 F.3d at 1347. In these hybrid cases, the court becomes a de novo fact-finder for issues on which the court accepts new evidence. Id. at 1347-48 (holding that "live testimony admitted on all matters that were before the Board triggers a de novo trial"). Moreover, the court need not afford deference to the Board's finding: "when live testimony is or has been admitted on an issue, the court becomes the fact-finder and is free to come to its own independent conclusion contrary to the Board." Id. at 1346-47 (acknowledging "the quality that is available only with the examination and cross-examination of live witnesses" that enables the court to reach a "distinct and more

informed conclusion"); see also <u>Agilent Techs. Inc. v. Affymetrix, Inc.</u>, 567 F.3d 1366 (Fed. Cir. 2009) ("In Section 146 actions, if the parties present new evidence to the district court that conflicts with the record before the Board, the district court must make *de novo* factual findings regarding this new evidence."). The litigants must be awarded a "full and fair opportunity to ventilate the issues." *Koninklijke Philips Elec.*, 590 F.3d at 1332.

# 2. Burden of Proof

The burden of proof in the interference proceeding is dependent on the filing dates of the competing patent applications. 37 C.F.R. § 41.207(a)(2) ("Priority may be proved by a preponderance of the evidence except a party must prove priority by clear and convincing evidence if the date of its earliest constructive reduction to practice is after the issue date of an involved patent or the publication date under 35 U.S.C. 122(b) of an involved application or patent"). When the interferences involve pending applications, the junior party has the burden of proving his case for priority by a preponderance of the evidence. *Morgan v. Hirsch*, 728 F.2d 1449, 1451 (Fed. Cir. 1984). When a party's application date is after another party's issuance or publication of a patent or application, the burden of proof is by clear and convincing evidence. *See Hitzeman v. Rutter*, 243 F.3rd 1345, 1353 (Fed. Cir. 2001).

Streck acknowledges that its patent had not been published or issued as a patent at the time R&D filed its application, and that the burden is on R&D to prove it was first to invent by a preponderance of the evidence.<sup>7</sup>

<sup>&</sup>lt;sup>7</sup>R&D's burden of proof in the Interference Action was significantly higher because the Streck patents were entitled to a presumption of validity in that case and R&D had to prove invalidity by clear and convincing evidence. See <u>Apotex USA</u>, <u>Inc. v. Merck & Co.</u>, 254 F.3d 1031, 1036 (Fed. Cir. 2001). The court will independently review those facts presented at trial and in the interference proceeding and will apply the preponderance of evidence standard in analyzing those facts.

# 3. Priority of Invention

A person is entitled to a patent unless "before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned. suppressed, or concealed it." 35 U.S.C. § 102(g)(2). The substantive law on priority in an interference action is the same as that applied in an infringement trial.8 *Hitzeman*, 243 F.3d 1345, 1353 (Fed. Cir. 2001) (noting that in determining priority of invention, the Board must consider the factors under 35 U.S.C. § 102(g), i.e., "not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other."). Accordingly, priority of invention is awarded to the first party to reduce an invention to practice unless the other party can show that it was the first to conceive of the invention and that it exercised reasonable diligence in later reducing that invention to practice. Cooper v. Goldfarb, 154 F.3d 1321, 1327 (Fed. Cir.1998). Priority, conception, and reduction to practice are questions of law that are based on subsidiary factual findings. Id.; see Mycogen Plant Science, Inc. v. Monsanto Co., 243 F.3rd 1316, 1332 (Fed. Cir. 2001) (stating that the first inventor is the one who first reduces an invention to practice unless the other party can show it was the first to conceive the invention and exercised reasonable diligence in reducing it to practice).

<sup>&</sup>lt;sup>8</sup>In the infringement trial, the jury was instructed that R&D had to "prove by clear and convincing evidence (1) that before [Dr. Ryan] reduced his invention to practice, Dr. Alan Johnson reduced to practice a product or method that included all of the elements of [the relevant claims of the patents at issue] and (2) that Dr. Alan Johnson did not abandon, suppress, or conceal his invention before October 18, 1999." Filing No. 319 in 8:06CV458, Final Jury Instructions, Instruction No. 20. Further, it was instructed that "[a]n invention requires both conception and reduction to practice. A claimed invention is reduced to practice when the inventor has shown and understands that it will work for its intended purpose or when it is fully described in a filed patent application." *Id.*, Final Jury Instruction No. 22.

Conception is the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice. 

Cooper v. Goldfarb, 154 F.3d at 1327. "Conception must include every feature or limitation of the claimed invention." 

Kridl v. McCormick, 105 F.3d 1446, 1449 (Fed. Cir. 1997). A general goal, research plan, or desirable result is not sufficient to constitute conception. 

Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1228 (Fed. Cir. 1994). 

Additionally, conception must be corroborated by a non-inventor. 

Bosies v. Benedict, 27 F.3d 539, 542-43 (Fed. Cir. 1994). 

Statements or recollections of non-inventor witnesses derived solely from the inventor are not sufficient corroboration. See Coleman v. Dines, 754 F.2d 353, 360 (Fed. Cir. 1985).

To establish an actual reduction to practice, an inventor must prove that (1) he constructed an embodiment that met all the limitations of the claimed invention and (2) he determined at that time that the invention would work for its intended purpose. *Mycogen*, 243 F.3d at 1332; *Cooper*, 154 F.3d at 1382. An invention is said to work for its intended purpose "when there is a demonstration of its workability or utility." *Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1367 (Fed. Cir. 2008). The demonstration required to determine if the invention worked for its intended purpose "depends on the particular facts of each case, with the court guided by a common sense approach in weighing the sufficiency of the testing." *Scott v. Finney*, 34 F.3d 1058, 1061 (Fed. Cir. 1994).

An inquiry into the sufficiency of testing is not what kind of test was conducted, but whether the test conducted shows that the invention would work as intended in its contemplated use. *Id.* at 1062 (stating that there must be a "correlation between testing conditions and actual use conditions"). There is no requirement, however, "that an

invention, when tested, be in a commercially satisfactory stage of development in order to reduce the invention to practice." <u>DSL Dynamic Sciences, Ltd. v. Union Switch & Signal, Inc.</u>, 928 F.2d 1122, 1126 (Fed. Cir. 1991). Testing need not show utility beyond a possibility of failure, but only "utility beyond a probability of failure." <u>Scott</u>, 34 F.3d at 1062 (citations omitted). "Once the invention has been shown to work for its intended purpose, reduction to practice is complete." <u>Loral Fairchild Corp. v. Matsushita Elec. Indus. Co.</u>, 266 F.3d 1358, 1362-63 (Fed. Cir. 2001).

Reductions to practice must be also corroborated by "independent corroborating evidence in addition to [the inventors] own statements and documents." *Hahn v. Wong*, 892 F.2d 1028, 1032-33 (Fed. Cir. 1989). Further, to establish a reduction to practice, the inventor must prove that he knew and appreciated the fact of the invention at the time. *Manning v. Paradis*, 296 F.3d 1098, 1102 (Fed. Cir. 2002) (noting that the court must determine whether the alleged inventor appreciated that "he had performed a process that worked for its intended purpose"). Importantly, "when testing is required to establish that the invention works for its intended purpose, the inventor must at the time appreciate that such testing is successful." *Id.* at 1104.

One who is first to invent nonetheless loses priority of invention if he thereafter abandons, suppresses or conceals the invention. <u>Lutzker v. Plet</u>, 843 F.2d 1364, 1366 (Fed. Cir. 1988). Abandonment, suppression, or concealment may be established either by proving that the inventor actively suppressed his invention from the public in order to prolong the period during which the invention is secret or by inference from an unreasonable delay in making the invention publicly known. <u>Paulik v. Rizkalla</u>, 760 F.2d 1270, 1273 (Fed. Cir. 1985) (en banc); <u>Apotex USA v. Merck & Co., Inc. 254 F.3d 1031</u>,

1038 (Fed. Cir. 2001) (recognizing two types of suppression or concealment—active and inferred). "Evidence that a first inventor was spurred to disclose by the activities of a second inventor has always been an important factor in priority determinations because it creates an inference that, but for the efforts of the second inventor, 'the public would never have gained knowledge of [the invention]." *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1567 (Fed. Cir. 1996) (quoting *Brokaw v. Vogel*, 429 F.2d 476, 480 (C.C.P.A. 1970).

#### B. ANALYSIS

The court first finds that undisputed evidence establishes that Dr. Ryan was the first to conceive the invention, and he did so in 1993. The court further finds that the evidence before the court establishes that Streck was the first to reduce the invention to practice, which it did beginning in 1997 and continuing into 1998 and 1999. R&D has not shown by a preponderance of evidence that its experiments in 1996 (Johnson Controls 1-4) amounted to successful reductions to practice.

Based on its observation of the witnesses and the evaluation of the evidence adduced at trial, the court credits the testimony of Mr. James Janik and Dr. Robert Langley over that of Dr. Elkin Simson. Recognizing that Dr. Simson is a well-regarded and renowned expert in the field of hematology, the court nonetheless must consider the fact that Dr. Simson took several inconsistent positions in the interference and infringement actions. R&D's reliance on the testimony of Dr. Elkin Simson, who has never developed a hematology control, to prove that its 1996 compositions worked for their intended purpose as a control is misplaced. Dr. Simson's testimony relates more to the issue of

<sup>&</sup>lt;sup>9</sup>These include his position on conception, as detailed above, and his declaration in the interference proceeding, based on analysis of scattergrams, that Streck's 1997 experiments were not successful reductions to practice. See Int. Ex. 2250 (Simson's Eighth Decl.) at 45-49, 56-60, 67-72, and 78-82.

the stability of the composition over time and not to the issue of accuracy of an instrument's measurements in light of potential interference between the various components in the control composition.

The evidence establishes that the difficulty in developing an integrated control was the tendency for the hematology instrument to recognize the reticulocyte analogs incorrectly and count them as white blood cells, resulting in an inaccurate result. Testimony adduced from numerous witnesses, including Dr. Simson, establishes that scattergrams are necessary in designing and developing a control in order to eliminate inaccuracy as a result of interference. The subject matter of the patent clearly relates to the design and development of a control for specific hematology analyzers, and not to the evaluation of a control from an end-user's perspective, which would involve reliance on assay values.

Dr. Simson's conclusions are undermined by the testimony of Dr. Langley and Mr. Janik, both of whom have developed controls. Both of these experts testified that it is necessary to analyze both stability data and the scattergram (which shows potential interference) in order to know and appreciate if a control being developed works for its intended purpose. The court agrees that it is not possible to conclude that a control composition works for its intended purpose without reference to a scattergram. Without a scattergram, or an analysis of the mathematical data underlying the scattergram as determined by the algorithm, one cannot tell whether there is interference. Interference is determined by an evaluation, not only of how the machine classifies the cells, but by how close the cells are to the "gates" that separate the cells according to the machine's algorithm. The conclusion that scattergram analysis is necessary is supported by evidence

that the hematology instrument manufacturers test prototype controls with scattergrams. There is no evidence that Dr. Johnson evaluated this sort of evidence in connection with the experiments he ran in 1996. Equally significant, if he did use scattergrams throughout his experiment, he did not retain sufficient documentation to corroborate his alleged invention.

The court finds the Board erred in its conclusion that review of scattergrams is not necessary for development of an integrated control. Its conclusion was based on the erroneous finding that "Dr. Johnson knew what he was putting into the analyzer and would have known if an unexpected value was coming out." There is no evidence of precisely what went into the compositions that Dr. Johnson later deemed successful. The court was not provided with evidence of the components of either the commercial or prototype compositions that were mixed with reticulocytes in the Johnson Controls 1 - 4 experiments. The evidence shows that the 3K product used in Johnson Controls 1 & 2 had to be completely redesigned because it did not work with the new technologies used in the Cell-Dyn 4000 instrument and the 5D product used in Johnson Controls 3 & 4 was a prototype that was later abandoned as unworkable. Further, the evidence establishes that Dr. Johnson had no basis for a belief that the "expected values" of the separate compositions would remain the same in combination with another composition, especially with respect to the instrument's recognition of reticulocytes and the five subpopulations of white cells.

Even if scattergram evidence were not essential, R&D's evidence of any reduction to practice would be thin. R&D's evidence consists mainly of the uncorroborated testimony of the inventor, Dr. Johnson, that he created a composition and it worked. Dr. Johnson's

testimony is supported by sparse data and little or no contemporaneous record-keeping with respect to the success or failure of the experiments. In contrast, the quality and quantity of Streck's evidence of the extensive experimentation that ultimately resulted in its patent and commercial controls, points out the deficiencies in R&D's showing.<sup>10</sup>

Streck's actions subsequent to its 1997 experiments lend support to the conclusion that a reduction to practice had occurred, while R&D's actions belie its assertion that it had a composition that worked for its intended purpose in 1996. Streck refined its invention, filed a patent application, and brought its product to market. R&D, on the other hand, abandoned the project. If R&D truly had a composition that worked, it would have been contrary to its economic interest not to attempt to further develop an integrated control, especially because of its alliance with Abbott. At the least, the evidence shows that even if Dr. Johnson had created a composition that worked for its intended purpose, Dr. Johnson and R&D did not appreciate the fact that the testing had been successful. Otherwise, it stands to reason that it would have pursued the project.

Moreover, R&D has not shown that its experiments in 1998 and 1999 related to the refinement of integrated, as opposed to individual, controls. Also, the evidence shows that R&D was spurred into performing whatever later work it did by the impending release of Streck's commercial product. Along with a dearth of evidence that supports a reduction to practice, there is also considerable evidence that weighs against the conclusion that Dr. Johnson's 1996 experiments resulted in a composition that worked. He later noted that samples tested on the Cell-Dyn 4000 showed unacceptable reticulocyte stability, and R&D's numerous later problems with buffers, diluents, and individual controls is not

<sup>&</sup>lt;sup>10</sup>Because the Board found that Dr. Johnson had reduced the invention to practice in 1996, it did not consider the evidence of Streck's reductions to practice.

consistent with an ability to successfully reduce their integrated control conception to

practice.

The court finds that R&D has not shown by a preponderance of evidence that its

1996 experiments resulted in a reduction to practice of its conception of an integrated

reticulocyte control. The evidence shows that Streck was the first to invent—that is, the

first to conceive, as well as the first to reduce to practice—an integrated reticulocyte

control.11

IT IS ORDERED:

1. The Decision of the Board of Patent Appeals and Interferences in Patent

Interference No. 105,522 is reversed.

2. The judgment of the Board of Patent Appeals and Interferences in Patent

Interference No. 105,522 is vacated.

3. This action is remanded for proceedings consistent with this opinion.

4. A judgment consistent with this Memorandum Opinion will be separately issued

this date.

DATED this 30<sup>th</sup> day of September, 2010.

BY THE COURT:

s/ Joseph F. Bataillon

Chief United States District Judge

<sup>11</sup>Alternatively, since it is undisputed that Streck was the first to conceive the invention, the evidence would also support awarding priority to Streck because, although second to reduce the conception to practice, it exercised reasonable diligence in reducing it to practice from the time just after the R&D's conception in 1995. Streck's inactivity from 1995 to early 1997 can be excused because there was no market for an integrated control until there was an instrument that could run one. Further, even if R&D could show that it was the first inventor, the evidence would supports an abandonment or concealment theory, since there is no evidence that links its work on individual controls to the development of an integrated control and there is evidence of spurring.

28

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